Congress of the United States Washington, DC 20515

September 25, 2008

Department of Health and Human Services Office of Public Health and Science Attn: Brenda Destro Hubert Humphrey Building 200 Independence Avenue SW Room 728E Washington, DC 20201

Re: RIN 0991-AB48

Dear Ms. Destro:

We are writing to strongly object to a rule proposed on August 26, 2008 by the Department of Health and Human Services (HHS) that will significantly undermine patients' access to vital health services and information. The ill-conceived and unnecessary proposed rule puts politics and ideology before quality health care: It would expand the ability of health care providers to withhold treatment, counseling, or medical information based on their religious or moral beliefs without regard for the needs of the patient. The proposed rule broadens the scope and reach of existing federal refusal laws beyond Congressional intent, while creating confusion and uncertainty about the rights and obligations of patients, doctors, and health care institutions—not merely in the area of reproductive health but throughout the U.S. health care system. Because the proposed rule is a threat to the health care of women, their families, and all Americans, we urge you to halt all efforts to move it forward.

Background

In the proposed rule, HHS purports to educate recipients of Department funds about their legal obligations under three statutes—often referred to as the Church Amendments (42 USC 300a-7), the Coats Amendment (42 USC 238n), and the Weldon Amendment (Consolidated Appropriations Act 2008, PL 110-161, Div. G, 508d). These laws give individuals and institutions the ability to refuse to provide, or prohibit requiring the performance or participation in, health services or research activities contrary to personal religious beliefs or moral convictions.

While HHS states that the intent of the regulation is to clarify existing law, its expansive language and ambiguity will likely have the opposite effect. Rather than clarify the law, the proposed rule will lead to confusion for health care providers, state and local governments, and research institutions—which will undoubtedly struggle with the uncertain interaction between this proposed regulation and existing state and federal laws that address these issues.

This proposed rule is a solution in search of a problem. The American Board of Obstetrics and Gynecology (ABOG) recently issued a public statement vehemently denying charges by HHS that ABOG has required physicians to violate their conscience rights by providing or referring patients for abortion—erroneous charges that HHS used as a basis for issuing this unnecessary

rule. ABOG has also called on HHS to hold a hearing to reveal, among other things, actual cases of misconduct that the rule is intended to address which, to date, HHS has failed to provide to the public.

The Proposed Rule Fails to Clarify that Birth Control is Not a Target

Under an earlier draft of this rule in mid-July, HHS defined the term "abortion" to include commonly used FDA-approved methods of birth control. Rather than allay concerns over this language by including a definition of abortion consistent with the consensus of the medical community and existing federal policy, the proposed rule drops the abortion definition entirely. When asked to clarify that the regulation does not apply to birth control, HHS Secretary Leavitt stated: "This regulation does not seek to resolve any ambiguity in that area."

The potential implications of this ambiguity are far-reaching. Like the leaked draft, the proposed rule leaves the door open for insurance plans, hospitals, and other entities to define abortion in any way they choose—including in ways that would include common forms of birth control. As a result, women could be denied access to birth control services, including counseling and information, even if state laws protect that access.

For example, if adopted, the proposed rule could undermine a state's ability to enforce its own law requiring insurance plans that cover prescription drugs to cover birth control. It could create confusion for states administering Medicaid and the Title X programs because of existing program requirements ensuring access to contraceptive counseling and services; and it could create an opening for hospitals to refuse to comply with state laws requiring that sexual assault survivors be offered emergency contraception. In short, the proposal may well complicate the administration of longstanding and vital federal family planning programs, as well as state laws adopted to protect access to contraception.

The Proposed Rule Fails to Even Mention the Careful Balance Struck by Civil Rights Law

This proposed rule allows any employee of a health care provider to refuse to treat any individual if doing so would violate his or her religious beliefs or moral convictions—without any mention of the needs of the patient. In doing so, the proposed rule fails to address serious questions as to whether its purpose is to upset the careful balance between respecting employees' religious beliefs and employers' ability to provide their patients with access to health care currently maintained in federal law under Title VII of the Civil Rights Act of 1964.

Title VII provides a balance between employers' need to accommodate their employees' religious beliefs and practices—including their refusal to participate in specific health care activities to which they have religious objections—with the needs of the people the employer must serve. Under Title VII, employers have a duty to reasonably accommodate an employee or applicant's religious beliefs or practices, unless doing so places an "undue hardship" on the employer's business. This law provides protection for individual belief while still ensuring patients' access to health care services. An extensive guidance just released in July 2008 by the Equal Employment Opportunity Commission (EEOC), the federal agency charged with the enforcement of Title VII and other key employment discrimination laws, discusses in great detail the scope of employers' obligations to accommodate the religious beliefs of their employees.

Because the proposed rule fails to even mention Title VII or the comprehensive EEOC guidance, it will likely cause confusion and uncertainty among employees, employers and patients regarding their rights surrounding these refusals. The rule does not, for example, say what steps

an institution must take to reasonably accommodate an individual health provider's religious objection, nor whether there are any circumstances at all when the needs of the employer or its clients outweighs such an objection. Instead, it simply includes language prohibiting discrimination in specific circumstances against those who perform or assist with, or who refuse to perform or assist with, certain health services, and ignores the inevitable confusion and potential conflict with other employment protections.

The Proposed Rule Undermines Patients' Access to Information, Counseling, and Referrals

If this proposed rule is implemented, women seeking services at a health care facility that receives direct or indirect funds from HHS may no longer be assured that they will receive information about all of their health care options, including – but not limited to – the option of safe and legal abortion care. The rule allows a broad range of health care providers and entities to refuse even to counsel patients about options—thus denying information critical to informed consent and referrals to any other source of information or services.

For some entities, the refusal to counsel patients for services or provide medical information and options could extend to *any medical treatment*, beyond reproductive health care. For example, an oncologist working in a federally funded prostate cancer treatment program could withhold information from a patient about the option of extracting and freezing sperm before cancer treatment, if the oncologist personally objects to assisted reproduction. Indeed, health care professionals might rely on this rule to justify their refusal to provide information or counseling on services from vaccination to blood transfusion to end-of-life pain management. This proposed rule should not stand in the way of the information patients need to make health care decisions for themselves and their families, nor should it undermine providers' legal and ethical requirements to obtain patients' informed consent. As it stands, it threatens to fundamentally undermine the relationship between providers and patients, who will have no way of knowing which services, information, or referrals they may have been denied.

The Proposed Rule Does Not Even Protect Patients in Emergency Situations

The rule fails to address the obligations of individuals and entities in the case of medical emergencies. For example, the federal Emergency Medical Treatment and Labor Act (EMTALA) requires hospitals to at least stabilize patients who come to the ER in medical emergencies. The proposed rule offers no answers as to whether avoiding "discrimination" against a health care provider should be allowed to trump the need to treat a patient in a medical emergency. At best, this failure will cause confusion among employers. At worst, it could place patients in need of emergency medical care in grave harm.

The Proposed Rule Extends Broad Refusal Rights to an Expansive Array of Individuals and Institutions

The proposed rule expands the universe of health care individuals and institutions that may refuse to provide services. It also broadens the scope of what falls under a refusal under the applicable law. The proposed definition of "assist in the performance" states that it includes "counseling, referral, training, and other arrangements for the procedure, health service, or research activity." Further, the definition of "workforce" extends the right to refuse not only to an entity's employees but also to volunteers and trainees.

Further, the regulation's definitions of "recipient" and "sub-recipient" would extend the laws' applicability even to "foreign or international organizations (such as agencies of the United

Nations)" without any reference or deference to existing federal law governing U.S. foreign policy. This could create confusion among federal agencies about which laws to follow and could lead to unforeseen foreign policy complications.

The Proposed Rule May Impede Biomedical and Behavioral Research

Finally, the proposed rule could have a substantial impact on research activities at federally-funded hospitals and academic, nonprofit and corporate research institutions. In the proposed rule, a broad array of HHS-funded entities, including post-graduate physician training programs, hospitals, laboratories, universities and think tanks, are prohibited from discriminating against any personnel who refuse to perform, or assist in, *any* research activity or service. Without additional guidance about how research institutions should balance the needs of their employees with the needs of their research programs—guidance along the lines of the long established framework provided currently to these institutions under Title VII—this proposed rule could adversely impact a wide range of research efforts.

The proposed rule is damaging to the health care of women, their families, and all Americans, and will only serve to cause havoc, not clarity, among employers and employees in the health care field. Again, we urge you to halt all efforts in moving forward with this rule.

Sincerely,

Nita M. Lowey

Member of Congress

Diana DeGette

cc:

Member of Congress

Louise Slaughter Member of Congress

Henry Waxman

Member of Congress

Department of Health and Human Services Secretary Michael Leavitt President George W. Bush

In hu Corine (from Gewill hadle Lacille Popel-Alland Joe 8. Lonamo hipi kongag Mut Weyl Howard L. Berman Jun Morm Yang L. actermon Rosa L. Delauno Melvin J. Worts Earl Humenaver Lymn Woolsey Ed faster Bill Descull Ja Ellen Hauscher Rue Relaturt Barbara Lee Bris Bun

Both t lah amolauana RIEA faetterm Danny R. Daris Elind L. Engel (Lih the Amfred D. Bolog/fr. Bob Frener Lacaettaka Warm Lindy Jamy Balduri Noma F. Edwards ande Canon norm Dicho

Here Cohn Jan Selmkushy M. Dunnit Alle Sin 10m Well Clarentsecon Harle Johnson John Hall Spin Cappe Dan Fan Rinda J. Sich John for Su Thoon Laku Emannel Mazie K. Heroso Jetcheld Bruen L. Buly

Kaul M. Sryalva Jose Labrack Court Shear Poorer Mil allerrember Michael E. Capum In Judy Anna d. Main Grace 7. Napolitación Sim Van Holle C. Dutch Ruppers berge Sall Marg Bethy Sutton Body Modern Potony 6 (us Campa Hildah. Solis Joe Baca Brack Elle

Jable Gib (.M) Modes Pomplee Thelley Cercley Allyson & Delwart Buan High Stext srae Jan M. June Kirsten E. Tillibrand Thin Tasen Delily Wosserman Schult Ser John Coroly Milastry Meddalo Dor's O. MASU my J Frank Pallone f.

John Lewis Michael A. ami Hothy Castor Clen B. Shiff Jeny Miney Mula Zaly MilhShongen Steven N. Noth Donald M. Fayer Eforms Hair Pin Cotorp Mills Kon Kind nselinn Bean Cardyn B. Malony

Carolyn Pelputurk Eddie Bernie Hurran

Dianes. Watson	
Card Slee-Porter	
Jan Schredwile	
Rush Holt	
Mally Pailone	
Josaf redam	
Janua du Becerra	
Mide J. Sez	
·	

LASI NAME	FIRST NAME	
(Member)	(Member)	STATE
Abercrombie	Neil	
Ackerman	Gary	Ž
Allen	Tom	МЕ
Andrews	Robert	2
Arcuri	Mike	×
Baca	Joe	\ S
Baird	Brian	WA
Baldwin	Tammy	IM
Bean	Melissa	=
Becerra	Xavier	S S
Berkley	Shelly	\geq
Berman	Howard	CA
Bishop	Tim	×
Bishop	Sanford	ВĞ
Blumenauer	Earl	OR
Braley	Bruce	
Brown	Corrine	4
Capps	Lois	CA
Capuano	Mike	MA
Carnahan	Russ	MO
Carson	Andre	
Castor	Kathy	
Cohen	Stephen	:
Crowley	Joe	Ž
Davis	Susan	CA
Davis	Danny	
DeGette	Diana	00
Delahunt	William	MA
DeLauro	Rosa	CT
Dicks	Norm	WA
Edwards	Donna	1 1
Emanuel	Rahm	!-

_	
c	`
•	`

Engel	Eliot	λN
Farr	Sam	_ \
Fattah	Chaka	PA
Filner	Bob	ξ. V
Giffords	Gabrielle	AZ
Gillibrand	Kirsten	×
Gonzalez	Charlie	
Green	Gene	×
Green	Gene	×
Grijalva	Raul	AZ
Hall	John	Ž
Harman	Jane	CA
Higgins	Brian	×
Hinchey	Maurice	Ž
Hirono	Mazie	: : :
Hodes	Paul	三
Hooley	Darlene	CA
Inslee	Jay	WA
Israel	Steve	≥
Jackson, Jr	Jesse	
Johnson	Hank	GA
Kind	Ron	X
Larsen	Rick	WA
Fee	Barbara	S
Levin	Sander	₹
Lewis	John	ВA
Loebsack	Dave	≝
Lofgren	Zoe	CA
Lowey	Nita	Ž
Maloney	Carolyn	Ż
Matsui	Doris	CA
McCarthy	Carolyn	Ż
McCollum	Betty	Z.
McDermott	Jim	WA

		•
•	٦	
•		•

McGovern	mil.
McNerny	
Miller	1
Miller	: : : : : : : : : : : : : : : : : : :
Mitchell	Harry A7
Moore	i ;
Moore	S
Moran	1
Murphy	
Murphy	Chris
Nadler	Jerry
Napolitano	Grace
Pallone	•
Pallone	
Pascrell	
Pastor	Ed
Payne	Donald
Price	David
Robal-Allard	Lucille
Rothman	Steve
Ruppersberger	Dutch
Rush	Robert
Sanchez	Linda
Schakowsky	Jan
Schiff	Adam
Schwartz	Allyson
Serrano	Jose
Shea-Porter	Carol
Sires	Albiro
Slaughter	
Smith	Adam
Solis	Hilda
Sutton	
Tauscher	Ellen

nompson	Mike	S
	Ш	≥
Fsongas	N. S.	Δ×
Jdall	Mark	00
/an Hollen	Chris	M
Nalz	Tim	
Nasserman-Shultz	Debbie	ī
Natson	Dianne	
Natt	Mel	S
Vaxman	Henry	CA
Veiner	Anthony	1
Velch	Peter	
Vexler	Robert	
Voolsey	Lynn	Ϋ́